

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91250143
Party	Defendant Theragen, Inc.
Correspondence Address	LYNN E RZONCA BALLARD SPAHR LLP 1735 MARKET STREET 51ST FLOOR PHILADELPHIA, PA 19103-7599 UNITED STATES Primary Email: tmdocketing@ballardspahr.com Secondary Email(s): rzoncal@ballardspahr.com 215-864-8109
Submission	Testimony For Defendant
Filer's Name	Lynn Rzonca
Filer's email	rzoncal@ballardspahr.com, tupjak@ballardspahr.com, auerbachb@ballardspahr.com, tmdocketing@ballardspahr.com
Signature	/Lynn Rzonca/
Date	09/16/2020
Attachments	Theragen Declaration - FINAL.PDF(2890996 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

THERAGUN, LLC,

:

Opposer

:

Opposition No. 91250143

v.

:

Serial Nos. 88/369,252; 88/369,266

:

Marks: THERAGEN and  Theragen

THERAGEN, INC.,

:

Applicant

:

DECLARATION OF J. CHRIS MCAULIFFE

1. My name is J. Chris McAuliffe. I am the Chief Executive Officer at Theragen, Inc. ("Theragen").

2. I have personal knowledge of the facts set forth in this Declaration and can testify competently to the truth of each of the statements herein.

3. I understand that Theragun, LLC ("Opposer") alleges that Theragen's mark THERAGEN, as applied for in Theragen's trademark Application Serial No. 88/369,252, and Theragen's mark THERAGEN & Design, as applied for in Theragen's Application Serial No. 88/369,266 (together, "Theragen's Marks"), both covering Theragen's Goods (defined below), are likely to cause confusion, mistake, or deception with respect to Theragun's claimed mark.

4. To my knowledge, there has been no actual consumer confusion regarding Theragen and Opposer's company to date, nor has there been any consumer confusion regarding Theragen's and Opposer's respective products.

5. Theragen is a medical device company that develops effective and safe therapeutic technologies for healing and pain relief.

6. Theragen first began using "Theragen" as a trade name in 2014.

7. Theragen began developing medical devices in 2014.



8. Theragen's medical devices include noninvasive medical devices, specifically neuromuscular electrical stimulation devices and transcutaneous electrical nerve stimulation devices. Theragen's medical devices do not use percussive or mechanical energy to deliver therapy.

9. Theragen intends to use the Theragen Marks on and in association with its electrostimulatory devices that target certain portions of the body, namely, a patient's knees, spine, or upper extremities, and use topical electrical stimulation in order to provide tissue, bone, and/or joint therapy as pain treatment (the "Theragen Goods"). Again, the Theragen Goods do not use any percussive force to provide therapy, making them starkly different from Opposer's products.

10. The Theragen Goods are not handheld or manually supported while in operation, but are specifically placed on a certain targeted portion of the body with a conductive medium attached to the skin, and are designed to only treat certain designated types of tissue. Theragen Goods remain in one location on the body while delivering therapy.

11. The Theragen Goods require approval from the United States Food and Drug Administration (the "FDA"). Approval from the FDA specifically defines how Theragen may market the proposed use of the Theragen Goods, as well as the functions of the Theragen Goods themselves (the "Indications for Use"). Theragen's representations to the FDA are binding and cannot be altered. Were Theragen to market or use its devices beyond its representations to the FDA, Theragen would be practicing off-label marketing, which is prohibited by FDA and could result in criminal charges against a manufacturer.

12. Attached as Exhibits A through C are documents submitted by Bio-Medical Research Ltd. ("BMR"), Theragen's predecessor in interest, to the FDA. These documents reflect the representations made to the FDA regarding the products Theragen intends to identify using the Theragen Marks. BMR assigned all rights, including the intellectual property rights, to these products, along with their FDA registrations, to Theragen on August 16, 2015.

13. As outlined in the FDA submissions, Indications for Use for the Theragen Goods

are “based on the principles of NMES and TENS. NMES may be defined as the application of **electrical** stimulation of the peripheral nervous system to contract a muscle, either through the direct activation of the motor neurons in the mixed peripheral nerve, or indirectly through reflex recruitment. TENS can be defined as a pain therapy based on the application of **electrical** stimuli to the skin via stimulation of the nerve fibers.” See Exhibit C at 5 (emphasis added).

14. In addition to the FDA review of Theragen’s submissions, the Theragen Goods will be reviewed and classified by Medicare as part of its Pricing, Data Analysis, and Coding system and assigned a code under the Healthcare Common Procedure Coding System. The codes provide structured guidelines on how the Theragen Goods can be billed, and consequently, how the Theragen Goods can be prescribed. Should Theragen wish to be reimbursed under the Medicare program, it will be required to only bill its products as electrostimulatory devices, and will only be able to sell them via prescription.

15. As indicated by Theragen’s FDA submissions and the Medicare classifications, the Theragen Goods are available for sale by prescription only. See Exhibit A, B and C. The Theragen Goods cannot be sold online, either by Theragen itself or by third-party retailers.

16. The Theragen Goods will not be made available or sold to the general public “over the counter,” but rather, are prescribed by credentialed, licensed medical professionals, reimbursed within the U.S. medical healthcare reimbursement community, and ultimately purchased by sophisticated consumers who have previously consulted with a medical professional, such as surgeon or licensed prescriber, to obtain a prescription for a Theragen Good. The Theragen Goods are prescribed in response to a specific medical condition. In certain circumstances, licensed practitioners may pre-order a certain amount of bulk Theragen Goods for ready availability at their respective clinics, but may only provide the Theragen Goods to a particular patient only after the patient has been diagnosed with a condition requiring the application of a Theragen Good.

17. Intended consumers for Theragen’s Goods are prescribing doctors, physical therapists, and licensed medical professionals, as well as individual consumers who obtain

prescriptions from their doctors, physical therapists, or medical professionals.

18. I am familiar with Opposer's products, and know that the products are marketed directly to consumers "over the counter". Opposer's products do not require a prescription from a licensed medical professional prior to purchase, and can be purchased directly from Opposer's website and from third-party retailers such as Amazon.

19. I declare under penalty of perjury that the foregoing is true and correct.

Dated: September 16, 2020



J. CHRIS MCAULIFFE

Exhibit A

K112934

JAN 20 2012



Bio-Medical Research Ltd.

Parkmore Business Park West, Galway, Ireland
Tel: +353 (0)91 774300 - Fax: +353 (0)91 774301

This 510k Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

Name: Anne-Marie Keenan
Address: Bio-Medical Research Ltd.,
Parkmore Business Park, West
Galway, Ireland
Telephone: +353 91 774300
Fax: +353 91 774302
E-Mail: akeenan@bnrl.ie
Prepared: December 22, 2011

2. Device Name

Trade Name of Device: Neurotech Recovery
Common Name: Conductive Garment
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Product Code: GXY
Device Class: 2

3. Identification of Equivalent Legally Marketed Device

510(k) Number: K070142
Manufacturer: Bio-Medical Research Ltd.
Trade Name: System-Abs

510(k) Number: K082190
Manufacturer: Bio-Medical Research Ltd.
Trade Name: Baxolve XP Conductive Garment

4. Description of Device

The Neurotech Recovery is a non-sterile, reusable conductive garment for single patient use only. It acts as an interface between the adhesive electrodes on the patient's skin and the Neurotech Plus electrical stimulator which provides Neuromuscular Electrical Stimulation (NMES) or Transcutaneous Electrical Nerve Stimulation (TENS).

The Neurotech Recovery is available as two options, each targeting separate areas of the human anatomy;

1. The Neurotech Recovery for the lower back which is constructed of the following materials; Main Panels: 89% Nylon & 11% Spandex laminated to Polyurethane, Silver Trace, Binding: 100% Cotton & Hook and Loop Fastener: 100% Nylon
2. The Neurotech Recovery for the abdomen which is constructed of the following materials; Main Panels: 100% Nylon, Binding: 82% Nylon & 18% Elastane, Hook and Loop Fastener: 100% Nylon & Foam Padding: 100% Polyurethane

Included with each Neurotech Recovery conductive garment are conductive gel pads, an extender strap and instructions for use. The device is intended be available by prescription only.

5. Statement of Intended Use/Indications for Use

Intended Use:

The Neurotech Recovery is intended for home use. Sale of the device has been restricted to sale under a prescription order from a licensed practitioner.

Indications for Use:

The Neurotech Recovery – Back Conductive Garment for the back and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the low back.

The Neurotech Recovery – Back Conductive Garment for the abdomen and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the abdominal area.

6. Summary of Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Neurotech Recovery device. No clinical tests have been submitted as part of this premarket notification. The Neurotech Plus device complies with the following international standards:

- I.S. EN ISO 14971 2007 Medical devices - Application of risk management to medical devices
- EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
- EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
- EN ISO 10993-10:2002 & Amendment 1 2006 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2002/Amd. 1:2006)

Based on substantial equivalence analysis carried out between the proposed Neurotech Recovery device and the listed predicates, we believe that the proposed device is safe and effective.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Bio-Medical Research Ltd.
c/o Ms. Anne-Marie Keenan
Quality & Regulatory Engineer
Parkmore Business Park West
Galway,
Ireland

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JAN 20 2012

Re: K112934

Trade/Device Name: Neurotech Recovery
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 21, 2011
Received: December 22, 2011

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

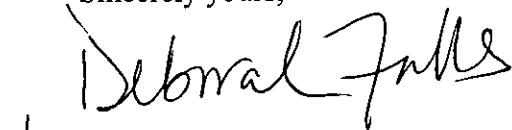
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112934

Device Name: Neurotech Recovery-Back

Indications for Use:

The Neurotech Recovery – Back Conductive Garment for the back and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the low back.

The Neurotech Recovery – Back Conductive Garment for the abdomen and associated accessories are indicated for use with Neurotech Stimulators to facilitate the frequent and correct positioning and repositioning of large, multiple, and/or difficult to reach stimulation sites associated with the abdominal area.

Prescription Use X _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112934

Exhibit B



bio-medical research ltd.

K112258

This 510k Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

Name: Anne-Marie Keenan
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Prepared: November ,2, 2011

2. Device Name and Regulation

Trade Name of Device: Neurotech Plus, Type 413
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Product Code: GZJ, NYN, IPF
Device Class: II

3. Identification of Equivalent Legally Marketed Device

510(k) Number: K082011
Manufacturer: Bio-Medical Research Ltd.
Trade Name: MediStim XP, Type 281

510(k) Number: K082011
Manufacturer: Bio-Medical Research Ltd.
Trade Name: MediTens XP, Type 458

510(k) Number: K061516
Manufacturer: Compex Technologies
Trade Name: Staodyn® Max, Model 4470

510(k) Number: K971437
Manufacturer: Murray Electronics
Trade Name: Bionicare Stimulator System Model Bio-1000

4. Description of Device

The Neurotech Plus is a portable, two-channel; battery operated system which can provide both Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS). The device is intended be available by prescription only. Included with the Neurotech Plus control unit, are a lead wire assembly, electrodes and instructions for use.

The Neurotech Plus contains ten program sets which have been each allocated an individual type number. Seven of these types offer a combination of NMES and TENS programs. There are two types which offer only NMES programs and one which has only TENS programs.

The lead-wire assembly contains the ID chip (EEPROM) that identifies the required program set. Each of the program set options are pre-programmed during manufacturing and no access to the configuration is available to either the end user or clinician. When each lead wire is connected to the unit and the outputs (A, B, C or D) to the electrodes, the two channels may be operated independently through the unit. Detailed diagrams for correct device usage and placement of the electrodes are available as part of the instructions for use.

5. Statement of Intended Use/Indications for Use

Intended Use: Dependent on the program chosen, the Neurotech Plus, Type 413 can deliver Neuromuscular Electrical Stimulation (NMES) for the activation of muscle for rehabilitation

and/or Transcutaneous Electrical Nerve Stimulation (TENS) for the activation of nerves for neuromodulation and management of pain.

Indications for Use:

Models 431, 432, 433, 434, 436, 439, & 440 offer a combination of NMES or TENS programs.

NMES Indications for Use

- Maintain or increase the range of motion
- Prevention or retardation of disuse atrophy
- Re-educate muscles
- Relax muscle spasms
- Increase local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

TENS Indications for Use

- Symptomatic relief and management of chronic, intractable pain
- Relief of pain associated with arthritis
- Adjunctive treatment in the management of post-surgical and post-trauma pain
- Adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee (models 431, 432, 433 only)

Models 437, 441 (NMES only indications for use)

- Maintain or increase the range of motion
- Prevention or retardation of disuse atrophy
- Re-educate muscles
- Relax muscle spasms
- Increase local blood circulation
- Prevention of venous thrombosis of the calf muscles immediately after surgery

Model 438 (TENS only indications for use)

- Symptomatic relief and management of chronic, intractable pain
- Relief of pain associated with arthritis
- Adjunctive treatment in the management of post-surgical and post-trauma pain

Sale of the device has been restricted to sale under a prescription order from a licensed practitioner.

6. Summary of Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Neurotech Plus device. No new clinical tests have been submitted as part of this premarket notification.

The Neurotech Plus device complies with the following international standards:

- IEC 60601-1 (1998) + A1 (1991) + A2 (1995) Medical Electrical Equipment - Part 1: General Requirements for Safety.
- IEC 60601-2-10 (1987) + A1 (2001) Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
- IEC 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests
- I.S. EN ISO 14971 2007

6.1 Program Sets

Tables 6.1.1 to 6.1.10 show the program parameters for each model of the Neurotech Plus.

Table 6.1+1 Model 431	Screen Text	Intensity	Rate (Hz or fps)	Pulse Width (usec)	Cont (sec.)	Relax (sec.)	Ramp Up	Ramp Down	Additional Functions	Treatment Time
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Table 6.1+1 Model 431							Treatment Time (minutes)			
	Screen Text	Intensity	Rate (Hz or pps)	Pulse Width (usec)	Cont (sec.)	Relax (sec.)	Ramp Up (sec.)	Ramp Down (sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adj	125 ± 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 250 for 3 seconds of cycle time (see Note 1)	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time (see Note 1)	150					Open
2	P2	Adj	99	200					Burst Toggle – 4 Hz, 250 usec Activation and output remains constant after pressing the burst button. Press Burst again to cancel. No ramp up/down will be implemented (See note 2)	Open
3	P3	Adj	Ch 1: 4 Ch 2: 125	200					Criss-cross Function, Burst – Ch1 125 Hz, 200 usec & Ch2 125 Hz, 200 usec. Activation and output remains constant for 10 minutes after burst button pressed. No ramp up/down will be implemented (See note 2)	Open
4	P4	Adj	4	250					Burst – 125 Hz, 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented (See note 2)	Open
5	P5	Adj	50	300	5	15	1.0	0.5		30
6	P6	Adj	50	300	5	10	1.0	0.5	Trigger	30
7	P7	Adj	50	300	5	5	1.0	0.5	Trigger	30
8	P8	Adj	35	300	5	10	1.0	0.5	Trigger	30
9	P9	Adj	8	300	5	5	1.0	0.5	Trigger	20
10	P10	Adj	100	100					Trigger	90
			70	200	5	15	1.0	0.5		10
			100	100						90
			70	200	5	15	1.0	0.5		20
			100	100						90

Table 6.1.2
Model 432

Table 6.1.2 Model 432		Screen Text	Intensity	Rate (Hz or pps)	Pulse Width (usec)	Contract (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adj	125 to 4; modulates (decreases) between 125 to 4 in 1/2 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 1/2 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time							Open
2	P2	Adj	99	200						Burst -4Hz, 250 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented.	Open
3	P3	Adj	Ch 1: 4 Ch 2: 125	200						Cross-cross Function, Burst – Ch1 125 Hz, 200 usec & Ch2 125 Hz, 200 usec. Activation and output remains constant for 10 minutes after burst button pressed. No ramp up/down will be implemented. (See note 2)	Open
4	P4	Adj	4	250						Burst -125Hz, 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented	Open
5	P5	Adj	50	300	5	15	1.0	0.5		Trigger	30
6	P6	Adj	50	300	5	10	1.0	0.5		Trigger	30
7	P7	Adj	50	300	5	5	1.0	0.5		Trigger	30
8	P8	Adj	35	300	5	10	1.0	0.5		Trigger	20
9	P9	Adj	8	300	5	5	1.0	.5		Trigger	20
10	P10	Adj	100	100						Trigger	70
			70	200	5	15	1.0	0.5			10
			100	200	5	15	1.0	0.5			20
			70	200	5	15	1.0	0.5			20
			100	100							70

Table 6.1.3
Model 433

	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time						Open
2	P2	Adjustable		125	175				Burst – Frequency of 4 Hz, pulse width of 250 usec. Activation and output remains constant while pressing burst button. Will ramp down over 3 sec. and up over 3 sec.	Open
3	P3	Adjustable		4	250				Burst – Frequency of 125 Hz, pulse width of 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented.	Open
4	P4	Adjustable		50	300	5	15	1.0	0.5	Trigger
5	P5	Adjustable		50	300	5	10	1.0	0.5	Trigger
6	P6	Adjustable		50	300	5	5	1.0	0.5	Trigger
7	P7	Adjustable		35	300	5	10	1.0	0.5	Trigger
8	P8	Adjustable		8	300	5	5	1.0	0.5	Trigger
9	P9	Adjustable		100	100					20
10	P10	Adjustable		70	200	5	15	1.0	0.5	70
										20

Table 6.1.4 Model 434		Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	80	120	Continuous		2				Open
2	P2	Adjustable	2	180	Stimulation		2				Open
3	P3	Adjustable	80	70 - 120	Continuous		2				Open
4	P4	Adjustable	80/2	180	Stimulation		2				Open
5	P5	Adjustable	9/2	300	Continuous		2				20
6	P6	Adjustable	8	300	Stimulation		5	1.0	0.5	Trigger	20
7	P7	Adjustable	35	300		5	10	1.0	0.5	Trigger	30
8	P8	Adjustable	50	300		5	15	1.0	0.5	Trigger	30
9	P9	Adjustable	50	300		5	10	1.0	0.5	Trigger	30
10	P10	Adjustable	50	300		5	5	1.0	0.5	Trigger	30

Table 6.1.5 Model 436	Screen Text	Intensity	Rate (Hz or PPS)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time	NA	NA	NA	NA	None	Open
2	P2	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	50 to 100; modulates (increases) between 50 to 100 in 12 second cycle – remains at 50 for 3 seconds and 100 for 3 seconds of cycle time	NA	NA	NA	NA	None	Open
3	P3	Adjustable	125	150	NA	NA	NA	NA	Burst – Frequency is 80hz, pulse width 300 usec with 8 pulses per burst;	Open
4	P4	Adjustable	80	300	10	25 (Remove Beep)	1.5	1.5	Trigger	30
5	P5	Adjustable	50	300	10	20 (Remove Beep)	1.5	1.5	Trigger	30
6	P6	Adjustable	35	300	5	5	1.5	1.5	Trigger	30

Table 6.1.6 Model 437		Duration	Frequency	Pulse Width	Ramp-Up time	Contract Time	Ramp Down Time	Relax time
Program 1	20 minutes	60Hz	200 \square s	2seconds	3 seconds	2 seconds	5 seconds	5 seconds
Program2	25 minutes	55Hz	225 \square s	2seconds	3 seconds	2 seconds	5 seconds	5 seconds
Program 3	30 minutes	55Hz	250 \square s	2seconds	3 seconds	2 seconds	5 seconds	5 seconds
Program 4	40 minutes	50Hz	270 \square s	2seconds	3 seconds	2 seconds	5 seconds	5 seconds

Table 6.1.7 Model 438		Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Pulse	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time	NA	45
2	P2	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	50 to 100; modulates (increases) between 50 to 100 in 12 second cycle – remains at 50 for 3 seconds and 100 for 3 seconds of cycle time	50 to 100; modulates (increases) between 50 to 100 in 12 second cycle – remains at 50 for 3 seconds and 100 for 3 seconds of cycle time	NA	45
3	P3	Adjustable	125	175	175	NA	45
4	P4	Adjustable	4	250	250	NA	45
5	P5	Adjustable	Channel 1 – 4 Channel 2 – 125	175	175	NA	45
6	P6	Adjustable	80	175	175	8 pulses per burst; 2 bursts per second	45
7	P7	Adjustable	125 to 50; modulates (decreases) between 125 and 50 in 8 second cycle (4/4)	175	175	NA	45
8	P8	Adjustable		125	250 to 150; modulates (decreases) between 250 and 150 in 8 second cycle (4/4)	NA	45
9	P9	Adjustable	125 to 50; modulates (decreases) between 125 to 50 in 6 second cycle (3/3)	50 to 100; modulates (increases) between 50 to 100 in 6 second cycle (3/3)	50 to 100; modulates (decreases) between 50 to 100 in 6 second cycle (3/3)	NA	45
10	P10	Adjustable	125 to 50; modulates (decreases) between 125 and 50 in 10 second cycle (5/5)	150 to 250; modulates (increases) between 150 and 250 in 10 second cycle (5/5)	150 to 250; modulates (increases) between 150 and 250 in 10 second cycle (5/5)	NA	45

Table 6.1.8 Model 439		Screen Text	Intensity	Rate (Hz or Pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	50	300	5	5	1.0	0.5	0.5	Trigger	30
2	P2	Adjustable	50	300	10	10	1.0	1.0	1.0	Trigger	30
3	P3	Adjustable	50	300	10	20	1.5	1.0	1.0	Trigger	30
4	P4	Adjustable	50	300	10	30	1.5	1.0	1.0	Trigger	30
5	P5	Adjustable	35	250	8	25	1.5	1.0	1.0	Trigger	30
6	P6	Adjustable	.35	300	5	5	1.0	1.0	1.0	Trigger	30
7	P7	Adjustable	10	250	10	10	1.5	1.0	1.0	Trigger	30
8	P8	Adjustable	4	250						Burst -125 Hz, 175 usec. Activation and output remains constant while pressing burst button. Will ramp up over 3 sec. and down over 3 sec	45
9	P9	Adjustable	125	175						No-trigger	45
10	P10	Adjustable	125 to 4;	150 to 250;	modulates (increases) between 125 to 4 in 12 second cycle – remains at 125 for 3 sec. and 4 sec. for 3 sec. of cycle time					No-trigger	45

Table 6.1.9 Model 440		Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle - remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle - remains at 150 for 3 seconds and 250 for 3 seconds of cycle time							Open
2	P2	Adjustable	99 to 50; modulates (decreases) between 99 and 50 in 8 second cycle (4/4)	150 to 250; modulates (increases) between 150 to 250 in 8 second cycle (4/4)							Open
3	P3	Adjustable	125	175							Cross-cross Function (See note 3)
4	P4	Adjustable	4	250							
5	P5	Adjustable	50	300	5	10	1.0	0.5		Trigger	30
6	P6	Adjustable	50	300	10	10	1.0	0.5		Trigger	30
7	P7	Adjustable	50	300	10	20	1.0	0.5		Trigger	30
8	P8	Adjustable	50	300	10	30	1.0	0.5		Trigger	30
9	P8	Adjustable	35	300	5	5	1.0	0.5		Trigger	20
10	P10	Adjustable	10	300	10	10	1.0	0.5		Trigger	20

Table 6.1.10 Model 441	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
1	P1	Adjustable	50	300	5	10	1.0	0.5	Trigger	20
2	P2	Adjustable	50	300	10	10	1.0	0.5	Trigger	20
3	P3	Adjustable	50	300	10	20	1.0	0.5	Trigger	20
4	P4	Adjustable	50	300	10	30	1.0	0.5	Trigger	20
5	P5	Adjustable	35	300	5	5	1.0	0.5	Trigger	20
6	P6	Adjustable	4	300	Continuous Stimulation					
7	P7	Adjustable	10	300	20	5	1.5	0.5	No-Trigger	20
8	P8	Adjustable	70	300	10	50	1.0	0.5	Trigger	20
9	P9	Adjustable	99	300	5	30	1.0	0.5	trigger	30

7. Substantial Equivalence Comparison Tables

Each model of the Neurotech Plus, Type 413 device has been compared to it's predicate device at the worst case program. Based on comparative analysis carried out between the proposed Neurotech Plus and the listed predicates, we believe that the proposed device is as safe, as effective and performs as well or better than the listed predicates.

Table 7.1

Mode or Program Name (For calculation of maximum rms current, and power density)	Neurotech Plus Model 431	Predicate Device Staodyn Max K961516	Predicate Device Staodyn Max K971437	Predicate Bionicare K971437	Predicate MediTens K082011
Waveform (e.g pulsed monophasic, biphasic)	Plan 3 (Highest Output)	Program E (Highest output)	Only has 1 mode	Program 3 99Hz, 150µS	
Shape (e.g rectangular, spike, rectified sinusoidal)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Monophasic	Pulsed, symmetric, biphasic	
Maximum Output Voltage (volts)(+/- 10%)	Rectangular, with interphase interval	Rectangular	Exponential, Spike	Rectangular, with interphase interval	
Maximum Output Current (specify units)(+/- 10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	12V 500Ω	37.5V @ 500 Ω	
RMS Output Voltage (volts)(+/- 10%)	75.0V @ 2 kΩ	Not available	Not available	70.0V@ 2 kΩ	
	70.3V @ 10 kΩ	Not available	Not available	71.8V @ 10 kΩ	
	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	24mA @ 500Ω	75.0mA @ 500 Ω	
	37.5mA @ 2 kΩ	Not available	Not available	35.0mA @ 500 Ω	
	7.0mA @ 10 kΩ	Not available	Not available	7.0mA @ 10 kΩ	
	7.8V @ 500 Ω	8.9V @ 500 Ω	4.3V	6.5V@500Ω	
	16.8V @ 2 kΩ	Not available	Not available	14.2V@2kΩ	
	7.9V @ 10 kΩ.	Not available	Not available	4.95V@10kΩ	
Duration of primary (depolarizing) phase (usec)	15.7mA @ 500 Ω	17.8mA @ 500 Ω	8.6mA	13mA@500Ω	
Pulse Duration (usec)	8.4mA @ 2 kΩ	Not available	Not available	7.1mA@2kΩ	
Frequency (Hz)[or Rate (pps)]	0.8mA @ 10 kΩ	Not available	Not available	0.5mA@10kΩ	
For multiphasic waveforms only:	Symmetrical phases?	250uS	60-350uS	640 µS	150uS
	Phase duration (include	400-600uS (uS both phases + 100µS interphase delay)	700uS (350 uS both phases)	640 µS	400µS
		4 to 125Hz	80 to 125 Hz	100 Hz	4 to 99 Hz
	Yes	Yes	N/A	N/A	Yes
	100 to 250µS	60-350uS	N/A	N/A	100 to 150uS

Table 7.1

	Neurotech Plus Model 431	Predicate Device StandyMax K061516	Predicate Device Bionicare K971437	Predicate MediTens K082011
units) state range, if applicable)(both phases, if asymmetrical)				
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	0 µC @ 500 Ω	0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	21 µC @ 500Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	10.5 to 17.5 µC @ 500 Ω	9 to 21 µC @ 500 Ω	21 µC @ 500Ω	7.5 to 11.25 µC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) {@ 500 Ω Where T is the duration of averaging for worst case (highest) output}	0.80mA/cm ² (T=1sec)	Program E Using 2" square electrode =17.8 mA/25 cm ² = 0.71 mA/cm ²	0.08 mA/cm ² i.e. 8.6mA/108 cm ² Using 12 x 9 cm electrodes	0.672mA/cm ² 5cm round electrode
Maximum Average Current (average absolute value), mA { @ 500 Ω}	3.5mA	5.3mA	2.1mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }	6.2mW (T=1sec) 50mm round electrode	6.3 mW/cm ² Program E Using 2" square electrode	0.34 mW/cm ²	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A	N/A
		Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts		Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second	N/A	N/A	N/A	N/A
(c) Burst duration (seconds)	N/A	0.09	N/A	N/A
(d) Duty Cycle [Line (b) x Line (c)]	N/A	.18	N/A	N/A
ON Time (seconds)	N/A	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A	N/A

Table 7.2

Mode or Program Name	Neurotech Plus Model 432	Predicately Device Staodyn Max K061516	Predicately Device Bionicare K971437	Predicately MediTens K082011
	Plan 3	Program E (highest output)	Only has 1 mode	Program 3 (95Hz, 150µS)
Waveform (e.g. pulsed monophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Monophasic	Pulsed, symmetric, biphasic
Shape (e.g. rectangular, spike, rectified sinusoidal)	Rectangular, with interphase interval	Rectangular	Exponential, Spike	Rectangular, with interphase interval
Maximum Output Voltage (volts)(+/- 10%)	35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ	30.0V @ 500 Ω Not available Not available	12V 500Ω Not available Not available	37.5V @ 500 Ω 70.0V @ 2 kΩ 71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0mA @ 10 kΩ	60.0 mA @ 500 Ω Not available Not available	24mA @ 500Ω Not available Not available	75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)	7.8V @ 500 Ω	8.9V @ 500 Ω	4.3V	6.5V@500Ω
	16.8V @ 2 kΩ	Not available	Not available	14.2V@2kΩ
	7.9V @ 10 kΩ	Not available	Not available	4.95V@10kΩ
RMS Output Current (specify units)(+/- 10%)	15.7mA @ 500 Ω	17.8mA @ 500 Ω	8.6mA	13mA@500Ω
	8.4mA @ 2 kΩ	Not available	Not available	7.1mA@2kΩ
Duration of primary (depolarizing) phase (usec)	0.8mA @ 10 kΩ	Not available	Not available	0.5mA@10kΩ
Pulse Duration (usec)	150-250uS	60-350uS	640 µS	150uS
Frequency (Hz) or Rate (pps)]	400-600uS (uS both phases + 100µS interphase delay)	700uS (350 uS both phases)	640 µS	400µS
For multiphasic waveforms only:	Symmetrical phases? Phase duration (include units) state range, if	Yes 60-350uS	N/A N/A	Both phases 4 to 99 Hz Yes 100 to 150uS

Table 7.2

	Neurotech Plus Model 432	Predicate Device Staodyn Max K061516	Predicate Device Bionicare K971437	Predicate Meditens K082011
applicable)(both phases, if asymmetrical)	0 µC @ 500 Ω	0 µC @ 500 Ω	21 µC @ 500Ω	0 µC @ 500 Ω
Net Charge(microcouombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	14.0 µC @ 500 Ω	9 to 21 µC @ 500 Ω	21 µC @ 500Ω	7.5 to 11.25 µC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) {@ 500 Ω Where T is the output duration}	0.80mA/cm ² (T=1sec)	Program E Using 2" square electrode =17.8 mA/25 cm ² = 0.7 mA/ cm ²	0.08 mA/cm ² i.e. 8.6mA/0.8 cm ² Using 12 x 9 cm electrodes	0.672mA/cm ² 5cm round electrode
Maximum Average Current (average absolute value), mA { @ 500 Ω}	3.5mA	5.3mA	2.1mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration]	6.2mW (T=1sec)	6.3 mW/cm ² Program E Using 2" square electrode	0.34 mW/cm ²	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts	N/A	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second	N/A	2	N/A	N/A
(c) Burst duration (seconds)	N/A	0.09	N/A	N/A
(d) Duty Cycle [Line (b) x Line (c)]	N/A	.18	N/A	N/A
ON Time (seconds)	N/A	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A

Table 7.3

Mode or Program Name	Neurotech Plus Model 433	Predicate Device Staodyn Max K01516	Predicate Device Bionicare K971437	Predicate MediTens K082011
Waveform (e.g pulsed monophasic, biphasic)	Plan 2	Program E (highest output)	Only has 1 mode	Program 3 99Hz, 150µS
Shape (e.g rectangular, spike, rectified sinusoidal)	Rectangular, with interphase interval	Pulsed, symmetric, biphasic Rectangular	Pulsed, Monophasic Exponential, Spike	Pulsed, symmetric, biphasic Rectangular, with interphase interval
Maximum Output Voltage (volts) (+/- 10%)	35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ	30.0V @ 500 Ω Not available	12V 500Ω Not available	37.5V @ 500 Ω 70.0V @ 2 kΩ
Maximum Output Current (specify units) (+/- 10%)	70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0mA @ 10 kΩ	60.0 mA @ 500 Ω Not available	24mA @ 500Ω Not available	75.0mA @ 500 Ω 35.0mA @ 500 Ω
RMS Output Voltage (volts)(+/- 10%)	7.3V @ 500 Ω	8.9V @ 500 Ω	4.3V Estimated assuming a square pulse shape 0.64ms	6.5V@500Ω
RMS Output Current (specify units)(+/- 10%)	15.7V @ 2 kΩ	Not available	Not available	14.2V@2kΩ
RMS Output Current (specify units)(+/- 10%)	7.9V @ 10 kΩ	17.8mA @ 500 Ω	8.6mA	4.95V @ 10kΩ 13mA @ 500Ω
Duration of primary (depolarizing) phase (usec)	7.8mA @ 2 kΩ	Not available	Not available	7.1mA@2kΩ
Pulse Duration (usec)	0.8mA @ 10 kΩ	Not available	Not available	0.5mA@ 10kΩ 150µS
Frequency (Hz)[or Rate (pps)]	150-250uS 400-600uS (uS both phases + 100uS interphase delay)	60-350uS 700uS (350 uS both phases)	640 µS 80 to 125 Hz	400uS Both phases 4 to 99 Hz
For multiphasic waveforms only:	Symmetrical phases? Phase duration (include units) state range, if	Yes 60-350uS	N/A	Yes 100 to 150uS

Table 7.3

	Neurotech Plus Model 433	Predicate Device Stoddyn Max K061516	Predicate Device Bionicare K971437	Predicate MediTens K082011
applicable)(both phases, if asymmetrical)				
Net Charge(microcoulombs (μ C) per pulse) (if zero, state method of achieving zero net charge.)	$0 \mu\text{C} @ 500 \Omega$	$0 \mu\text{C} @ 500 \Omega$	$21 \mu\text{C} @ 500 \Omega$	$0 \mu\text{C} @ 500 \Omega$
	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.	Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (μ C)	$12.3 \mu\text{C} @ 500 \Omega$	$9 \text{ to } 21 \mu\text{C} @ 500 \Omega$	$21 \mu\text{C} @ 500 \Omega$	$7.5 \text{ to } 11.25 \mu\text{C} @ 500 \Omega$
Maximum Current Density (mA/cm^2 , r.m.s) {@ 500 Ω Where T is the output duration}	$0.75 \text{mA/cm}^2 (T=1\text{sec})$	Program E Using 2" square electrode $=17.8 \text{ mA}/25 \text{ cm}^2$ $=0.71 \text{mA}/\text{cm}^2$	0.08 mA/cm^2 i.e. $8.6 \text{mA}/108 \text{ cm}^2$ Using 12 x 9 cm electrodes	0.672mA/cm^2 5cm round electrode
Maximum Average Current (average absolute value), mA { @ 500 Ω }	3.06mA	5.3mA	2.1mA	2.25mA
Maximum Average Power Density, (W/cm^2), (using smallest electrode conductive surface area) {@ 500 Ω Where T is the output duration}	$5.5 \text{mW} (T=1\text{sec})$	6.3 mW/cm^2 Program E Using 2" square electrode	0.34 mW/cm^2	4.4mW/cm^2 50mm round electrode
Burst Mode (i.e., pulse trains):	(a) Pulses per burst N/A	8	N/A	N/A
	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts			Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second	N/A	2	N/A	N/A
(c) Burst duration (seconds)	N/A	0.09	N/A	N/A
(d) Duty Cycle [Line (b) x Line (c)]	N/A	.18	N/A	N/A
ON Time (seconds)	N/A	N/A	N/A	N/A
Off Time (seconds)	N/A	N/A	N/A	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A

Table 7.4

Mode or Program Name	Neurotech Plus Model 434	Predicate Device Staodyn Max K061516	Predicate Device MediTens K082011	Predicate Device Program 3 (99Hz, 150µS)
	Plan 4	Program E (Highest output)		
Waveform (e.g. pulsed monophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	
Shape (e.g. rectangular, spike, rectified sinusoidal)	Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval	
Maximum Output Voltage (volts) (+/- 10%)	35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ 70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0mA @ 10 kΩ 5.4V @ 500 Ω 11.6V @ 2 kΩ 6.3V @ 10 kΩ 10.8mA @ 500 Ω 5.8mA @ 2 kΩ 0.6mA @ 10 kΩ 120-180µS 340-460µS (uS both phases + 100µS interphase delay)	30.0V @ 500 Ω Not available Not available 60.0 mA @ 500 Ω Not available Not available 8.9V @ 500 Ω Not available Not available 17.8mA @ 500 Ω Not available Not available 60-350µS 2-80Hz	37.5V @ 500 Ω 70.0V @ 2 kΩ 71.8V @ 10 kΩ 75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ 6.5V @ 500Ω 14.2V @ 2kΩ 4.95V @ 10kΩ 13mA @ 500Ω 7.1mA @ 2kΩ 0.5mA @ 10kΩ 150µS 400µS Both phases	Program 3 (99Hz, 150µS)
Maximum Output Current (specify units) (+/- 10%)				
RMS Output Voltage (volts) (+/- 10%)				
RMS Output Current (specify units) (+/- 10%)				
Duration of primary (depolarizing) phase (usec)				
Pulse Duration (usec)				
Frequency (Hz) or Rate (pps)]	Symmetrical waveforms only:	Yes	Yes	Yes
	Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	100 to 250µS	60-350µS	100 to 150µS
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)		0 µC @ 500Ω Symmetric, biphasic and leading polarity	0 µC @ 500Ω Symmetric, biphasic and	0 µC @ 500Ω Symmetric, biphasic and leading

	alternates for each successive pulse.	leading polarity alternates for each successive pulse.	polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	10.5 <u>C</u> @ 500 Ω	9 to 21 μ C @ 500 Ω	7.5 to 11.25 μ C @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) {@ 500 Ω Where T is the output duration}	0.55mA/cm ² (T=1sec)	Program E Using 2" square electrode $=17.8 \text{ mA}/25\text{ cm}^2$ $= 0.71 \text{ mA}/\text{cm}^2$	0.672mA/cm ² 5cm round electrode
Maximum Average Current (average absolute value), mA {@ 500 Ω }	1.68mA	5.3mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) {@ 500 Ω Where T is the output duration}	3.0mW (T=1sec)	6.3 mW/cm ² Program E Using 2" square electrode	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):	(a) Pulses per burst Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts	N/A 8	N/A Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second		2	
(c) Burst duration (seconds)		0.09	
(d) Duty Cycle [Line (b) x Line (c)]		.18	
ON Time (seconds)	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A

Table 7.5

Mode or Program Name	Neurotech Plus Model 436	Predicate Device Staodyn Max K061516	Neurotech Plus Model 436	Predicate Device MediStim XP K082011
Waveform (e.g pulsed monophasic, biphasic)	Plan 3 (TENS)		Plan 4 (NMES)	
Shape (e.g rectangular, spike, rectified sinusoidal)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Maximum Output Voltage (volts)(+/- 10%)	Rectangular, with interphase interval 35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ 70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0mA @ 10 kΩ 6.8V @ 500 Ω 14.5V @ 2 kΩ 7.8V @ 10 kΩ 13.6mA @ 500 Ω 7.3mA @ 2 kΩ 0.8mA @ 10 kΩ 50-250uS	Rectangular 30.0V @ 500 Ω Not available 60.0 mA @ 500 Ω Not available 70.3V @ 10 kΩ 70.0mA @ 500 Ω Not available 7.0mA @ 10 kΩ Not available 16.4V @ 2 kΩ Not available 6.3V @ 10 kΩ Not available 8.2mA @ 2 kΩ Not available 60-350uS (350 uS both phases + 100μS interphase delay) 4-125Hz	Rectangular, with interphase interval 35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ 70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0mA @ 10 kΩ 7.0mA @ 10 kΩ 7.7V @ 500 Ω 16.4V @ 2 kΩ 7.1V @ 10 kΩ 15.3mA @ 500 Ω 12.1V @ 2 kΩ 7.1V @ 10 kΩ 13.0mA @ 500 Ω 6.0mA @ 2 kΩ 0.6mA @ 10 kΩ 300uS 35-80Hz	Rectangular, with interphase interval 37.5V @ 500 Ω 70.0V@ 2 kΩ 71.8V @ 10 kΩ 75.0mA @ 500 Ω 35.0mA @ 2 kΩ 35.0mA @ 500 Ω 7.0mA @ 10 kΩ 6.5 V @ 500 Ω 12.1V @ 2 kΩ 7.1V @ 10 kΩ 13.0mA @ 500 Ω 6.0mA @ 2 kΩ 0.7mA @ 10 kΩ 150-300uS 2-100Hz
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates	0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates	0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates

Table 7.5

	Neurotech Plus Model 436	Predatec Device Staodyn Max K061516	Neurotech Plus Model 436	Predatec Device MedStim XP K082011
Maximum Phase Charge (μ C)	for each successive pulse. 10.5μ C @ 500 Ω	for each successive pulse. 10.5μ C @ 500 Ω	for each successive pulse. 21.0μ C @ 500 Ω	for each successive pulse. 21.0μ C @ 500 Ω
Maximum Current Density (mA/cm^2 , r.m.s) {@ 500 Ω Where T is the output duration}	$0.69\text{mA/cm}^2(T=1\text{sec})$	$0.69\text{mA/cm}^2(T=1\text{sec})$	$0.78\text{mA/cm}^2(T=1\text{sec})$	$0.78\text{mA/cm}^2(T=1\text{sec})$
Maximum Average Current (average absolute value), mA {@ 500 Ω }	2.63mA	Not available	3.36mA	Not available
Maximum Average Power Density, (W/ cm^2), (using smallest electrode conductive surface area) {@ 500 Ω Where T is the output duration}	4.7mW (T=1sec)	Not available	6.0mW (T=1sec)	Not available
Burst Mode (i.e., pulse trains):	(a) Pulses per burst (b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle [Line (b) x Line (c)]	N/A N/A N/A N/A	N/A N/A N/A N/A	N/A N/A N/A N/A
ON Time (seconds)		N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A

Table 7.6

Mode or Program Name	Neurotech Plus Model 437	Predicate Device MediStim XP K082011						
Waveform (e.g. pulsed monophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic						
Shape (e.g. rectangular, spike, rectified sinusoidal)-	Rectangular, with interphase interval	Rectangular, with interphase interval						
Maximum Output Voltage (volts)(+/- 10%)	35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ 70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0 mA @ 10 kΩ 5.8V @ 500 Ω 12.4V @ 2 kΩ 5.2V @ 10 kΩ 11.6mA @ 500 Ω 6.2mA @ 2 kΩ 0.5mA @ 10 kΩ	37.5V @ 500 Ω 70.0V @ 2 kΩ 71.8V @ 10 kΩ 75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ 6.5 V @ 500 Ω 12.1V @ 2 kΩ 7.1V @ 10 kΩ 13.0mA @ 500 Ω 6.0mA @ 2 kΩ 0.7mA @ 10 kΩ						
Maximum Output Current (specify units)(+/- 10%)	200-270uS	150-300uS						
RMS Output Voltage (volts)(+/- 10%)	500-640 uS (100 uS both phases + 100uS interphase delay)	400-700uS(100 uS both phases + 100uS interphase delay)						
RMS Output Current (specify units)(+/- 10%)	50-60Hz	2-100Hz						
Duration of primary (depolarizing) phase (usec)								
Pulse Duration (usec)								
Frequency (Hz) or Rate (pps)]								
For multiphasic waveforms only:	<table border="1"> <tr> <td>Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)</td> <td>Symmetrical phases?</td> </tr> <tr> <td>N/A</td> <td>N/A</td> </tr> <tr> <td></td> <td>N/A</td> </tr> </table>		Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	Symmetrical phases?	N/A	N/A		N/A
Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	Symmetrical phases?							
N/A	N/A							
	N/A							
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	0 μC @ 500 Ω	0 μC @ 500 Ω						
Maximum Phase Charge (uC)	17.5μC @ 500 Ω	21.0μC @ 500 Ω						
Maximum Current Density (mA/cm ² , r.m.s) (@ 500 Ω Where T is the output duration)	0.59mA/cm ² (T=1sec)							

Table 7.6

		Neurotech Plus Model 437	Predate Device MediStim XP K082011
Maximum Average Current (average absolute value), mA { @ 500 Ω }		1.93mA	Not available
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }		3.4mW (T=1sec)	Not available
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A
	(b) Bursts per second	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A	N/A
ON Time (seconds)		N/A	N/A
OFF Time (seconds)		N/A	N/A

Table 7.7

Mode or Program Name	Neurotech Plus Model 438	Predate Device Staodyn Max K061516
Waveform (e.g pulsed monophasic, biphasic)	Plan 8	
Shape (e.g rectangular, spike, rectified sinusoidal)	Pulsed, symmetric, biphasic Rectangular, with interphase interval	Pulsed, symmetric, biphasic Rectangular
Maximum Output Voltage (volts)(+/- 10%)	35.0V @ 500 Ω 75.0V @ 2 kΩ	30.0V @ 500 Ω Not available
Maximum Output Current (specify units)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω Not available
RMS Output Voltage (volts)(+/- 10%)	37.5mA @ 2 kΩ 7.0mA @ 10 kΩ	7.0mA @ 10 kΩ Not available
RMS Output Current (specify units)(+/- 10%)	8.7V @ 500 Ω 18.7V @ 2 kΩ 7.8V @ 10 kΩ	8.7V @ 500 Ω Not available Not available Not available
Duration of primary (depolarizing) phase (usec)	17.5mA @ 500 Ω 9.4mA @ 2 kΩ 0.8mA @ 10 kΩ	Not available Not available Not available
Pulse Duration (usec)	\$0-250uS 200-600uS (uS both phases + 100uS interphase delay)	60-350uS 700uS (350 uS both phases)
Frequency (Hz)[or Rate (pps)]	4-125Hz	
For multiphasic waveforms only:	Symmetrical phases? Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	N/A N/A N/A
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)		0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	17.5μC @ 500 Ω	0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Current Density (mA/cm ² , r.m.s)	0.89mA/cm ² (T=1sec)	

{ @ 500 Ω Where T is the output duration }	
Maximum Average Current (average absolute value), mA { @ 500 Ω }	4.38mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area)	7.8mW (T=1sec)
{ @ 500 Ω Where T is the output duration }	
Burst Mode (i.e., pulse trains):	
(a) Pulses per burst	N/A
(b) Bursts per second	N/A
(c) Burst duration (seconds)	N/A
(d) Duty Cycle [Line (b) x Line (c)]	N/A
ON Time (seconds)	N/A
OFF Time (seconds)	N/A

Table 7.8		Neurotech Plus Model 439	Predicate Device Stodyn Max K061516	Predicate MediTens K082011
Mode or Program Name		Plan 9 (TENS)	Program E (Highest output)	Program 3 99Hz, 150µS
Waveform (e.g pulsed monophasic, biphasic)		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)		Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval
Maximum Output Voltage (volts) (+/- 10%)		35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ	30.0V @ 500 Ω Not available Not available	37.5V @ 500 Ω 70.0V @ 2 kΩ 71.8V @ 10 kΩ
Maximum Output Current (specify units +/- 10%)		70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0mA @ 10 kΩ	60.0 mA @ 500 Ω Not available Not available	75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ
RMS Output Voltage (volts) (+/- 10%)		6.8V @ 500 Ω 14.6V @ 2 kΩ 7.8V @ 10 kΩ	8.9V @ 500 Ω Not available Not available	6.5V @ 500Ω 14.2V @ 2kΩ 4.95V @ 10kΩ
RMS Output Current (specify units (+/- 10%)		13.6mA @ 500 Ω 7.3mA @ 2 kΩ 0.8mA @ 10 kΩ	17.8mA @ 500 Ω Not available Not available	13mA @ 500Ω 7.1mA @ 2kΩ 0.5mA @ 10kΩ
Duration of primary (depolarizing) phase (usec) (usec)		150-250uS	400-600uS (uS both phases + 100µS interphase delay)	60-350uS 700uS (350 uS both phases)
Pulse Duration		4-125Hz	80 to 125 Hz	400µS Both phases 150uS
Frequency (Hz) or Rate (pps)]		Yes	Yes	Yes
For multiphasic waveforms only:	Phase Duration	100 to 250µS	60-350uS	100 to 150uS
Net Charge(microcolombs (uC) per pulse) (if zero, state method of achieving zero net charge.)		0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.	0 µC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)		10.6µC @ 500 Ω	9 to 21 µC @ 500 Ω	7.5 to 11.25 µC @ 500 Ω

Table 7.8

	Neurotech Plus Model 439	Predate Device Staodyn Max K061516	Predate Device MediTens K082011
Maximum Current Density (mA/cm ² , r.m.s) { @ 500 Ω Where T is the output duration}	0.70mA/cm ² (T=1sec)	Using 2" square electrode =17.8 mA/25 cm ² = 0.71mA/ cm ²	0.672mA/cm ² 5cm round electrode)
Maximum Average Current (average absolute value), mA { @ 500 Ω }	2.66mA	5.3mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) { @ 500 Ω Where T is the output duration }	4.7mW (T=1sec)	6.3mW/cm ² Program E Using 2" square electrode	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains): (a) Pulses per burst	N/A	8	N/A
	Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts		Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second		2	
(c) Burst duration (seconds)		0.09	
(d) Duty Cycle [Line (b) x Line (c)]		.18	
ON Time (seconds)	N/A.	N/A	N/A
Off Time (seconds)	N/A	N/A	N/A
Additional Features (specify, if applicable)	N/A	N/A	N/A

Table 7.9

	Neurotech Plus Model 440	Predicate Device Staodyn Max K061516	Predicate Device MediTens K082011
Mode or Program Name	Plan 9 (TENS)	Program E (Highest output)	Program 3 (99Hz, 150μS)
Waveform (e.g. pulsed monophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g. rectangular, spike, rectified sinusoidal)	Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval
Maximum Output Voltage (volts)(+/- 10%)	35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ	30.0V @ 500 Ω Not available Not available	37.5V @ 500 Ω 70.0V @ 2 kΩ 71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0mA @ 10 kΩ	60.0 mA @ 500 Ω Not available Not available	75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)	6.8V @ 500 Ω 14.6V @ 2 kΩ 7.8V @ 10 kΩ	8.9V @ 500 Ω Not available Not available	6.5V @ 500Ω 14.2V @ 2kΩ 4.95V @ 10kΩ
RMS Output Current (specify units)(+/- 10%)	13.6mA @ 500 Ω 7.3mA @ 2 kΩ 0.8mA @ 10 kΩ	17.8mA @ 500 Ω Not available Not available	13mA @ 500Ω 7.1mA @ 2kΩ 0.5mA @ 10kΩ
Duration of primary (depolarizing) phase (usec)	150-250uS	60-350uS	150uS
Pulse Duration (usec)	400-600uS (uS both phases + 100μS interphase delay)	700uS (350 uS both phases)	400μS Both phases
Frequency (Hz)[or Rate (pps)]	4-125Hz	80 to 125 Hz	4 to 99 Hz
For multiphasic waveforms only:	N/A N/A	Yes 100 to 250μS	Yes 100 to 150uS
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	0 μC @ 500 Ω	0 μC @ 500 Ω	0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	10.6μC @ 500 Ω	9 to 21 μC @ 500 Ω	7.5 to 11.25 μC @ 500 Ω
Maximum Current Density (mA/cm ² , r.m.s) { @ 500 Ω Where T is the output duration }	0.70mA/cm ² (T=1sec)	Program E Using 2" square electrode =17.8 mA/25 cm ²	0.672mA/cm ² 5cm round electrode

Table 7.9

	Neurotech Plus Model 440	Predicate Device Staodyn Max K061516	Predicate Device MediTens K082011
Maximum Average Current (average absolute value), mA { @ 500 Ω }	2.66mA	= 0.71mA/cm ² 5.3mA	2.25mA
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) I @ 500 Ω Where T is the output duration	4.7mW (T=1sec)	6.3 mW/cm ² Program E Using 2" square electrode	4.4mW/ cm ² 50mm round electrode
Burst Mode (i.e., pulse trains):	(a) Pulses per burst Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts	N/A 8	N/A Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
(b) Bursts per second		2	
(c) Burst duration (seconds)		0.09	
(d) Duty Cycle: [Line (b) x Line (c)]		.18	
ON Time (seconds)		N/A	N/A
OFF Time (seconds)		N/A	N/A
Additional Features (specify, if applicable)		N/A	N/A

Table 7.10

Mode or Program Name	Neurotech Plus Model 441	Predate Device MedStim XP K82011
Waveform (e.g. pulsed monophasic, biphasic)	Plan 9 (NMES)	
Shape (e.g. rectangular, spike, rectified sinusoidal)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Maximum Output Voltage (volts) (+/- 10%)	35.0V @ 500 Ω 75.0V @ 2 kΩ 70.3V @ 10 kΩ	Rectangular, with interphase interval 37.5V @ 500 Ω 70.0V @ 2 kΩ 71.8V @ 10 kΩ
Maximum Output Current (specify units) (+/- 10%)	70.0mA @ 500 Ω 37.5mA @ 2 kΩ 7.0 mA @ 10 kΩ	75.0mA @ 500 Ω 35.0mA @ 500 Ω 7.0mA @ 10 kΩ
RMS Output Voltage (volts) (+/- 10%)	8.5V @ 500 Ω 18.3V @ 2 kΩ 7.0V @ 10 kΩ	6.5 V @ 500 Ω 12.1V @ 2 kΩ 7.1V @ 10 kΩ
RMS Output Current (specify units) (+/- 10%)	17.1mA @ 500 Ω 9.1mA @ 2 kΩ 0.7mA @ 10 kΩ	13.0mA @ 500 Ω 6.0mA @ 2 kΩ 0.7mA @ 10 kΩ
Duration of primary (depolarizing) phase (usec)	300uS	150-300uS
Pulse Duration (usec)	400uS (100 uS both phases + 100uS interphase delay)	400-700us(100 uS both phases + 100uS interphase delay)
Frequency (Hz) or Rate (pps)	10-99Hz	2-100Hz
For multiphasic waveforms only:	Symmetrical phases? Phase duration (include units) state range, if applicable)(both phases, if asymmetrical)	N/A N/A
Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving zero net charge.)	0 μC @ 500 Ω	0 μC @ 500 Ω Symmetric, biphasic and leading polarity alternates for each successive pulse.
Maximum Phase Charge (uC)	21.0μC @ 500 Ω	21.0μC @ 500 Ω

Maximum Current Density (mA/cm ² , r.m.s) {@ 500 Ω Where T is the output duration}	0.87mA/cm ² (T=1sec)		
Maximum Average Current (average absolute value), mA {@ 500 Ω}	4.16mA		Not available
Maximum Average Power Density, (W/ cm ²), (using smallest electrode conductive surface area) {@ 500 Ω Where T is the output duration}	7.4mW (T=1sec)		Not available
Burst Mode (i.e., pulse trains):			
(a) Pulses per burst	N/A		N/A
(b) Bursts per second	N/A		N/A
(c) Burst duration (seconds)	N/A		N/A
(d) Duty Cycle [Line (b) x Line (c)]	N/A		N/A
ON Time (seconds)	N/A		N/A
OFF Time (seconds)	N/A		N/A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Biomedical Research, LTD
c/o Ms. Anne-Marie Keenan
Quality & Regulatory Engineer
Parkmore Business Park West
Galway, Ireland

JAN - 9 2012

Re: K112258

Trade/Device Name: Neurotech Plus, Type 413

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous electrical nerve stimulator for pain relief

Regulatory Class: II

Product Code: GZJ, NYN, IPF

Dated: November 30, 2011

Received: December 5, 2011

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Malvina B. Eydelman, M.D.
Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112258

Device Name: Neurotech Plus, Type 413

Indications for Use: The Neurotech Plus device is indicated for the following:

In combination Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS) modes, models 431, 432, 433, 434, 436, 439 & 440:

NMES Indications	TENS Indications
Maintain or increase the range of motion	Symptomatic relief and management of chronic, intractable pain
Prevention or retardation of disuse atrophy	Relief of pain associated with arthritis
Re-educate muscles	Adjunctive treatment in the management of post-surgical and post-trauma pain
Relax muscle spasms	Adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee (models 431, 432 and 433 only)
Increase local blood circulation	
Prevention of venous thrombosis of the calf muscles immediately after surgery	

In Neuromuscular Electrical Stimulation (NMES) only mode, models 437 & 441:

NMES Indications
Maintain or increase the range of motion
Prevention or retardation of disuse atrophy
Re-educate muscles
Relax muscle spasms
Increase local blood circulation
Prevention of venous thrombosis of the calf muscles immediately after surgery

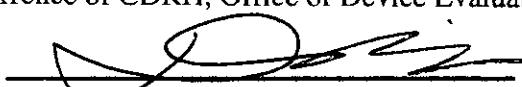
In Transcutaneous Electrical Nerve Stimulation (TENS) only mode, model 438:

TENS Indications
Symptomatic relief and management of chronic, intractable pain
Relief of pain associated with arthritis
Adjunctive treatment in the management of post-surgical and post-trauma pain

Prescription Use X _____ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K112258

Exhibit C

K110350



Bio-Medical Research Ltd.

Parkmore Business Park West, Galway, Ireland

Tel: +353 (0)91 774300 - Fax: +353 (0)91 774301

AUG - 3 2011

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

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Prepared: July 25, 2011.

2. Device Name

Trade Name of Device: Kneehab XP, Type 412/421
Common Name: Transcutaneous Electrical Nerve Stimulator
Powered Muscle Stimulator
Regulation Number: 21 CFR 882.5890
21 CFR 890.5850
Regulation Description: Transcutaneous electrical nerve stimulator for pain relief
Powered muscle stimulator
Product Code: IPF, GZJ, NYN
Device Class: 2

3. Identification of Equivalent Legally Marketed Device

510(k) Number: K083105
Manufacturer: Bio-Medical Research Ltd.
Trade Name: Kneehab XP Conductive Garment, Type 411

510(k) Number:	K082011
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	MediStim XP, Type 281
510(k) Number:	K082011
Manufacturer:	Bio-Medical Research Ltd.
Trade Name:	MediTens XP, Type 458
510(k) Number:	K061516
Manufacturer:	Compex Technologies, Inc
Trade Name:	Staodyn Max Preset
510(k) Number:	K021100
Manufacturer:	Empi
Trade Name:	300 PV Complete Electrotherapy System
510(k) Number:	K971437
Manufacturer:	BioniCare Medical Technologies
Trade Name:	Bionicare® Stimulator System

4. Description of Device

The Kneehab XP, Type 412/421 is a portable, battery operated, combination device which can provide both neuromuscular electronic stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). The device incorporates multipath®, a patented technology developed by neurotech® which enables the Kneehab XP Conductive Garment to deliver highly focused and accurate NMES muscle contractions. This device also provides a method of pain management and relief through the use of TENS technology.

The Kneehab XP pack consists of a rechargeable control unit, a left or right universally sized garment, a pack of custom adhesive electrodes, a battery charger and instructions for use. The garment is fastened around the thigh and above the kneecap and contains a connector socket into which the control unit is plugged. Power is derived from a 3.6V NiMH rechargeable battery pack that is pre-installed in the unit. A battery charger is included with

the device and the device cannot be used while being charged. The adhesive electrodes have an estimated usage capability of 20 sessions when used under the recommended conditions of use.

All internal connections of the unit are over molded to prevent moisture ingress. The user has no access to the wiring or connectors within the garment and is unable to alter the current path. There are nine treatment programs in total (six NMES and three TENS) with a duration of 20 minutes each. Program details are included in the instructions for use. For purposes of hygiene, the garment may be cleaned and instructions for device care are included in the user manual.

5. Statement of Intended Use and Indications for Use

Kneehab XP, Type 412/421 delivers stimulation based on the principles of NMES and TENS. NMES may be defined as the application of electrical stimulation of the peripheral nervous system to contract a muscle, either through the direct activation of the motor neurons in the mixed peripheral nerve, or indirectly through reflex recruitment. TENS can be defined as a pain therapy based on the application of electrical stimuli to the skin via stimulation of the nerve fibers.

In NMES mode (Programs 1-6), the Kneehab XP, Types 412/421, is indicated for use as follows:

1. Maintain or increase the range of motion.
2. Prevention or retardation of disuse atrophy
3. Re-educate muscles
4. Early post-surgical quadriceps strengthening and improved post surgical knee stability secondary to quadriceps strengthening
5. Relax muscle spasms
6. Increase blood circulation

Programs 1-6 use multipath technology.

Neuromuscular Electrical Stimulation (NMES) Programs on Kneehab XP:

Program Number	Duration (Minutes)	Frequency/Rate (Hz)	Pulse Width (μsec)	Ramp Up Time (seconds)	Contraction Time (seconds)	Ramp Down Time (seconds)	Relaxation Time (seconds)	Additional Function	Indication No.
P1	20	50	300-400	1	5	0.5	10	Trigger	4
P2	20	50	300-400	1	10	0.5	10	Trigger	1, 2, 3, 5, 6
P3	20	50	300-400	1	10	0.5	20	Trigger	1, 2, 3, 5, 6
P4	20	50	300-400	1	10	0.5	30	Trigger	1, 2, 3, 5, 6
P5	20	35	300-400	1	5	0.5	5	Trigger	1, 2, 3, 5, 6
P6	20	70	300-400	1	10	0.5	50	Trigger	1, 2, 3, 5, 6

In TENS Mode (Programs 7 - 10), the Kneehab XP, Type 412/421 is indicated for use as follows:

7. Provide symptomatic relief and management of chronic, intractable pain
8. Provide an adjunctive treatment in the management of acute, post-surgical or post-traumatic pain
9. Provide symptomatic relief and management of intractable pain and relief of pain associated with arthritis
10. Provide an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee
- 11.

Transcutaneous Electrical Nerve Stimulation (TENS) Programs on Kneehab XP:

Program Number	Duration (Minutes)	Frequency/Rate (Hz)	Pulse Width (μsec)	Ramp Up Time (seconds)	Contraction Time (seconds)	Ramp Down Time (seconds)	Relaxation Time (seconds)	Additional Function	Indication No.
P7	30	99	300	N/A	Continuous	N/A	N/A	No Trigger	7-10
P8	30	4	300	N/A	Continuous	N/A	N/A	No Trigger	7, 8, 9
P9	30	125	175	N/A	Continuous	N/A	N/A	No Trigger	7, 8, 9

6. Summary of Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Kneehab XP, Type 412/421 device. A summary of the technological characteristics of the new device in comparison to the predicate device has been included below:

General Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	Kneehab XP	Kneehab XP Conductive Garment	MediTens XP	MediStim XP	Staodyn Max	300 PV Complete Electrotherapy System	Bionicare® Stimulator System
510k Number:	K110350	K083105	K082011	K082011	K061516	K021100	K971437
Intended Use	The Kneehab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS).	The Kneehab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS).	The MediTens XP is intended to provide Transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS).	The Kneehab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS).	The Kneehab XP is intended to provide transcutaneous Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS).	The 300 PV is a multifunction electrotherapy device intended to provide Neuromuscular Electrical Stimulation (NMES), Transcutaneous Electrical Nerve Stimulation (TENS), Interferential Current Stimulation (IPS) and Functional Electrical Stimulation (FES).	The Bionicare is a battery operated TENS stimulator producing pulses at 100 Hz. Electrodes are applied to the knee and thigh.
Prescriptive Use	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Indications for Use	In NMES mode (Programs 1-6) the Kneehab XP is intended to: Maintain or increase range of motion, Prevention or retardation of disuse atrophy, Re-educate muscles, Early post-surgical quadriceps strengthening and improved post surgical knee stability secondary to quadriceps strengthening, Relax muscle spasms & Increase local blood circulation In TENS Mode (Programs 7 - 9) the Kneehab XP is intended to: Provide symptomatic relief and management of chronic, intractable pain, Provide an adjunctive treatment in the management of acute, post-surgical or post-traumatic pain, Provide	Muscle re-education of the quadriceps, Maintaining or increase range of motion of the knee joint, Prevention or retardation of disuse atrophy in the quadriceps, Early post-surgical quadriceps strengthening and improved post-surgical knee stability secondary to quadriceps strengthening & increasing local blood circulation.	The symptomatic relief and management of chronic intractable pain. It is also an adjunctive treatment in the management of post-surgical and post-traumatic pain. The device has no curative value and should only be used in conjunction with medical supervision.	Neuromuscular Electrical Stimulation (NMES) for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis and maintaining or increasing range of motion. Transcutaneous Electrical Nerve Stimulation (TENS) for an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.	The Staodyn® Max Preset Transcutaneous Electrical Nerve Stimulator Device is used for the symptomatic relief and management of chronic intractable pain and relief of pain associated with arthritis. It is also used as an adjunctive treatment in the management of post-surgical and post-traumatic pain. As a TENS device, the 300 PV is indicated for the following conditions: Symptomatic relief and management of chronic, intractable pain and Adjunctive treatment for post-surgical and post-trauma acute pain	(TENS/NMES Indications for use) As a NMES device, the 300 PV is indicated for the following conditions: Re-educating muscles, Relaxation of muscle spasms, Increasing local blood circulation, Retarding or preventing disuse atrophy, Maintaining or increasing range of motion & Prevention of venous thrombosis of the calf muscles immediately after surgery As a TENS device, the 300 PV is indicated for the following conditions: Symptomatic relief and management of chronic, intractable pain and Adjunctive treatment for post-surgical and post-trauma acute pain	Provide an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee

General Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	Kneehab XP	Kneehab XP Conductive Garment	MediTens XP [®]	MediStim XP [®]	Staodyn Max	300 PV Complete Electritherapy System	Bionicare [®] Stimulator System
510k Number:	K110350	K083105	K082011	K082011	K061516	K021100	K971437
	symptomatic relief and management of intractable pain. Relief of pain associated with arthritis. Program 7 provides an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee.						
Energy Used or Delivered:	3.6V NiMH Rechargeable Battery Pack	Same as proposed device	9V Battery (type 6LR61)	9V Battery (type 6LR61)	3 x AAA Batteries	2 x AA	9V Battery (type 6LR61)
Unit:	Constructed from injection moulded thermosetting plastic (ABS-PA-757).	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	9V Battery (type 6LR61)
Garment:	Contains an EEPROM, Outer Fabric: 100% Nylon, Inner Fabric: 70% Polychloroprene & 30% Polyurethane, Binding: 82% Nylon & 18% Elastane, Fastenings: 100% Nylon	Same as proposed device	Not Applicable (N/A)	N/A	N/A	N/A	Garment wraps around knee and thigh, contains conductive surfaces onto which conductive gel is applied.
Electrode	Electrode A: 194 cm ² , Electrode B: 74 cm ² , Electrode C: 83 cm ² and Electrode D: 66 cm ²	Same as proposed device	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9cm etc.	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9cm etc.	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9cm etc.	Industry standard electrodes 5 x 5cm & 7 cm round 5 cm x 9cm etc.	2 of 12 x 9 cm approx
Lead Wires:	Over-moulded SATA connector, splitting to 5 leads / studs.	Same as proposed device	Set of two (dark blue and light blue), each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes. Constructed of PVC insulated, containing 7-strand tinsel copper with interwoven Kevlar reinforcing fibers.	Set of two (dark blue and light blue), each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes. Constructed of PVC insulated, containing 7-strand tinsel copper with interwoven Kevlar reinforcing fibers.	Set of two, each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes.	Set of two, each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes.	Set of two, each lead wire has 2 wires and terminates with a 2mm moulded pin for connection to electrodes.
Charger:	PC/ABS, complies with IEC 60950 and UL 1950	Same as proposed device	N/A	N/A	N/A	YES, charges batteries external to unit	N/A
Standards Met	IEC 60601-1 (1998) & A1:	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not Available	Not Available

General Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	Kneehab XP	Kneehab XP Conductive Garment	MediTens XP	MediStim XP	Stadydy Max	300 PV Complete Electrotherapy System	Bionicare® Stimulator System
510k Number:	K110350	K083105	K082011	K082011	K061516	K021100	K971437
	1991, A2; 1995, IEC 60601-2-10 (1987) & A1: 2001, IEC 60601-1-2 (2001), ISO 14971:2007, ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2002 & A1:2006 21 CFR 898 21 CFR 801						
Biocompatibility	Electrodes - K000947	Same as proposed device	Electrodes - K970426, K874469 & K965194	Electrodes - K970426, K874469 & K965194	Not available	Not available	Not Available
Compatibility with the environment & other devices	Complies to IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility Requirements and tests	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not Available	Not Available
Sterility	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Electrical & Mechanical Safety	Complies to IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety & IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	Not available
Chemical Safety	MSDS Sheet (Electrode Gel)	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	Not available
Thermal Safety	Complies to IEC 60601-1 & IEC 60601-2-10	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Not available	Not available
Radiation Safety	N/A	N/A	N/A	N/A	Not available	Not available	Not available

UNIT Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	Kneehab XP	Kneehab XP Conductive Garment	MediTens XP	MediStim XP	Staodyn Max	300 PV Complete Electrotherapy System	
510k Number:	K110350	K083105	K082011	K082011	K061516	K021100	
Manufacturer	China Turnkey Solutions Logistics (Shenzhen) Co.,Putian Free Trade Zone, CHINA 518038	Same as proposed device	Same as proposed device	Same as proposed device	Compex Technologies	Empi 599 Cardigan Road St. Paul, Minnesota 55126-4099	BionCare Medical Technologies, Inc., 47 R Loveton Circle Sparks, MD 21152
-Method of line Isolation	No line connection	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device
Patient Leakage Current	N/A	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	No line connection
No. of Output Modes	1	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Several, eg Hi Volt, FES.	1
Waveform/Shape	Pulsed, Symmetrical, Biphasic, Rectangular with interphase interval	Same as proposed device	Same as proposed device	Same as proposed device	Symmetrical Biphasic Square	Asymmetric and Symmetric square wave options, Hi Volt pulse option; exponential spikes.	Monophasic spike shaped pulse
No. of Output Channels	2	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	2
Synch/Alternating?	Synchronous (Multiplexed)	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Synchronous and alternating	Synchronous
-Method of channel Isolation	Transistor	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Transformer	unknown
Regulated Current or Regulated Voltage	Regulated Current	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Claimed to be regulated voltage
Software/Firmware/ Microprocessor Control?	Yes	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device
Automatic Overload Trip?	Yes, current limited, indefinite short circuit allowed	Same as proposed device	Same as proposed device	Same as proposed device	Unknown	Unknown	unknown
Automatic No-Load Trip?	Yes	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	unknown
Automatic Shut Off?	Yes	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Same as proposed device	Unknown
Patient Override	Yes, pause button	Same as proposed device	Same as proposed device	Same as proposed device	Not available	Yes, Pause, FES modes	Yes stop button ends treatment

UNIT Comparison	Proposed Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Name of Device:	Kneehab XP	Kneehab XP Conductive Garment	MediTens XP	MediStim XP	Staodyn Max	300 PV Complete Electrotherapy System	
SI0k Number:	K110350	K083105	K082011	K082011	K061516	K021100	
Timer range (mins)	20 mins - open	Same as proposed device	Open	30 minutes - open	120 mins	5 mins to open.	Open
Weight (unit)	116g (inc. batteries)	Same as proposed device	142g (inc. batteries)	142g (inc. batteries)	145g	226g	136g
Dimensions (W x H x D)	60x23x115mm	Same as proposed device	105x68x28mm	105x68x28mm	2.5" x 5.25" x 1.0"	1.26" x 3.3" x 4.5"	95x64x30mm
Frequency/ Phase Duration of program with highest output power.	Program 7 99Hz 300µS	Program 1 50Hz 400 µS	Program 3 99 Hz 150µS	Program 3 50Hz 400 µS	Program A 100Hz 350µS	Custom User 2 150Hz 400µS	100Hz 640µS
Baseline to Peak Current	80mA @500Ω 28mA @2kΩ 3.9mA @10kΩ	80mA @500Ω 28mA @2kΩ 3.9mA @10kΩ	75mA @500Ω +/- 10% 35mA @2kΩ 7mA@10kΩ	75mA @500Ω +/- 10% 35mA @2kΩ 7mA@10kΩ	60mA @500Ω	100mA @500Ω	24mA @ 500Ω
Baseline to Peak Output Voltage	40.0V @500Ω 55.6V @2kΩ 39.3V @10kΩ	40.0V at 500 Ω 55.6V @ 2k Ω 39.3V at 10k Ω	37V @500Ω 70V @2kΩ 70V@10kΩ	37V @500Ω 70V @2kΩ 70V@10kΩ	30V @500Ω	50V @500Ω	12V 500Ω
Maximum RMS Output Voltage (+/-10%) V _{rms}	9.3 V @ 500 Ω 17.1V @ 2kΩ 14.1V @10kΩ	9.15V@ 500Ω 10.74V @ 2kΩ 5.65V@10kΩ	6.4 V @500Ω 12.1V @2kΩ 7 V@10kΩ	7.5V@500Ω 14 @2kΩ 7 V @10kΩ	8.85V @500Ω	10.5V @500Ω	4.3V Estimated assuming a square pulse shape 0-6ms
Maximum RMS Output Current (+/-10%) I _{rms}	18.6 mA@500 Ω 8.6 mA@ 2kΩ 1420 µA@10kΩ	18.3mA @ 500Ω 5.37mA @ 2kΩ 565µA@10kΩ	12.8mA @500Ω 6.1mA @2kΩ 700µA@10kΩ	15mA @500Ω 7 mA @2kΩ 490µA@10kΩ	15.9mA @500Ω	21mA @500Ω (As stated in device IFU, however is inconsistent with other stated parameters)	8.6mA
Pulse Width	640 µs -sum of both phases; 300µs +40 µs interphase interval	840µs (both phases max 400µS with interphase interval of 40µS)	300µS(sum of both phases; 150µS) (Prog 1)	800µS(sum of both phases; 400µS) (Prog A)	700µS - sum of both phases; 350µS (Prog A)	1200µS, sum of both 400µS phases and interphase interval	640 µS
Net Charge (µC per pulse)	0µC @ 500Ω	0µC @ 500Ω	0µC @ 500Ω	0µC @ 500Ω	<20µA		Not available
Maximum Phase Charge @500Ω (+/-20%)	24 µC @ 500Ω	32.8µC	10.5µC @ 500Ω	30 µC	21 µC @ 500Ω	40 µC	21 µC @ 500Ω
Maximum Current Density @500Ω	=18.6 mA/83 cm ² =0.22 mA/cm ²	0.22 mA/cm ²	Using 2" square electrode = 12.8 mA/25 cm ² = 0.5 mA/cm ²	Using 2" square electrode = 15 mA/25 cm ² = 0.6 mA/cm ²	Using 2" square electrode =15.9 mA/25 cm ² = 0.64mA/cm ²	Using 2" square electrode =21 mA/25 cm ² = 0.84mA/cm ²	Using 12 x 9 cm electrodes =8.6 mA/108 cm ² =0.08 mA/cm ²
Maximum Power Density @500Ω (using smallest electrode conductive surface area)	Program 2 2.1mW/cm ² @ 500Ω	2.55 mW/cm ²	3.3 mW/cm ²	4.5 mW/cm ²	2.9 mW/cm ²	8.8 mW/cm ²	0.34 mW/cm ²
Burst Mode (ie pulse trains)	YES, NMES on off cycle	Yes, NMES on off cycle	Yes, burst mode TENS	Yes, NMES on off cycle	Yes, burst mode TENS	Yes, NMES and TENS modes	Yes

7. Substantial Equivalence

Bio-Medical Research Ltd (BMR) has over 30 years experience in the research, design, manufacture and marketing of medical grade products for both muscle strengthening and pain relief. Bio-Medical Research Ltd. complies with 21 CFR 820 and is registered to I.S. EN ISO 13485:2003, Medical Device Quality Management System for the design, manufacture and distribution of electro-medical devices.

Kneehab XP, Type 412/421 device complies with the following international safety standards:

- IEC 60601-1 (1998) + A1: 1991, A2: 1995, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2 (2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility Requirements & Tests.
- IEC 60601-2-10 (1987) + A1: 2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

A risk management plan has been carried out to I.S. EN ISO 14971 2007.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Bio-Medical Research LTD.
c/o Anne Marie Keenan
Quality/Regulatory Engineer
Parkmore Business Park, West
Galway
Ireland EI

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Re: K110350

AUG - 3 2011

Trade/Device Name: Kneehab XP, Type 412/421

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous electrical nerve stimulator for pain relief

Regulatory Class: Class II

Product Codes: GZJ, IPF, NYN

Dated: June 24, 2011

Received: June 30, 2011

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

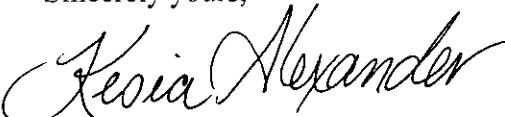
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

for
Enclosure

Indications for Use

510(k) Number (if known): K110350

Device Name: Kneehab XP, Type 412/421

Indications for Use:

The Kneehab XP, Type 412/421, Indications for use are as follows:

In NMES mode (Programs 1-6) the Kneehab XP is intended to:

- Maintain or increase the range of motion.
- Prevention or retardation of disuse atrophy
- Re-educate muscles
- Early post-surgical quadriceps strengthening and improved post surgical knee stability secondary to quadriceps strengthening
- Relax muscle spasms
- Increase blood circulation

In TENS Mode (Programs 7 - 9) the Kneehab XP is intended to:

- Provide symptomatic relief and management of chronic, intractable pain
- Provide an adjunctive treatment in the management of acute, post-surgical or post-traumatic pain
- Provide symptomatic relief and management of intractable pain and relief of pain associated with arthritis
- Provide an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee

Prescription Use X _____ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K110350